



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUN 1 2012

Re: CYSVIEW (previously Hexvix)  
Patent Nos. 7,247,655 and 7,348,361  
Docket Nos.: FDA-2011-E-0136  
Docket No.: FDA-2011-E-0133

The Honorable David J. Kappos  
Undersecretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 7,247,655, and 7,348,361 filed by Photocure ASA, under 35 U.S.C. section 156 *et seq.* We have reviewed the dates contained in the application and have determined the regulatory review period for CYSVIEW (previously Hexvix) (hexaminolevulinate hydrochloride), the human drug product claimed by the patents.

The total length of the regulatory review period for CYSVIEW is 3,103 days. Of this time, 2,770 days occurred during the testing phase and 333 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 30, 2001.

The applicant claims October 29, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 30, 2001, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 30, 2009.

FDA has verified the applicant's claim that the new drug application (NDA) for CYSVIEW (NDA 22-555) was submitted on June 30, 2009.

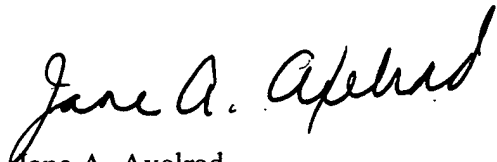
3. The date the application was approved: May 28, 2010.

FDA has verified the applicant's claim that NDA 22-555 was approved on May 28, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, reading "Jane A. Axelrad". The signature is fluid and cursive, with the first name "Jane" and last name "Axelrad" clearly legible.

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Deborah A. Somerville  
Kenyon & Kenyon LLP  
One Broadway  
New York, NY 10004